Remarks

Amendments to the Claims

The recitation "isolated" in claims 1, 5, and 13-19 is supported *inter alia* in paragraphs [0041], [0043], [00128], and in Section II, beginning on page 24..

Claim 3 is amended to be in independent form and to recite expression of a recombinant 14189 polypeptide. This amendment is supported in paragraphs [0013] and [00128].

The recitation of a cell-free assay mixture in claims 7 and 9 is supported in paragraph [00136].

Claims 5 and 10 are amended to be in independent form, incorporating the recitations of claims 1 and 9, respectively.

The amendments do not add new matter.

Objections to Claims 5 and 10

The Office Action objects to claims 5 and 10 as depending from rejected claims 1 and 9, respectively. Claims 5 and 10 have been amended to be in independent form, incorporating the recitations of claims 1 and 9, respectively. Please withdraw the objection.

Rejection Under 35 U.S.C. § 102(e)

Claims 1-4, 6-9, 11-19, 21-27, and 29-35 stand rejected under 35 U.S.C. § 102(e) as anticipated by Meyers (U.S. Patent 6,656,698). Applicants respectfully traverse the rejection.

Anticipation under 35 U.S.C. § 102 requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). The Office Action acknowledges that Meyers does not disclose a protein comprising SEQ ID NO:2, but states that the basis for the rejection is that "the measurement of kinase activity in human lung cells anticipates the claimed methods on the basis that the 14189 polypeptide of the instant claims is inherently in the human lung cells assayed by Meyers . . . ."

Meyers does not anticipate any of claims 1-4, 6-9, 11-19, 21-27, and 29-35. Independent claim 1 as amended recites a purified 14189 polypeptide, which Meyers does not disclose. Independent claims 7 and 9 as amended recites contacting "a cell-free assay mixture comprising a 14189 polypeptide . . . ."; Meyers does not disclose contacting a cell-free assay mixture with a 14189 polypeptide.

Please withdraw the rejection.

Non-Statutory Obviousness-Type Double Patenting Rejection

Claims 1-4, 6-9, 1-19, 21-27, and 29-35 stand rejected as obvious over claims 1-10 of Meyers. Applicants respectfully traverse the rejection.

A non-statutory obviousness-type double patenting rejection is analogous to an obviousness rejection under 35 U.S.C. § 103 except that the disclosure of the cited patent is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 600, footnote 4, 154 U.S.P.Q. 29, 34,

footnote 4 (C.C.P.A. 1967). Thus, the double patenting analysis parallels an analysis under 35 U.S.C. § 103(a). *In re Braat,* 937 F.2d 589, 592, 19 U.S.P.Q.2d 1289, 1291-92 (Fed. Cir. 1991). A *prima facie* case of obviousness over claims 1-10 requires the following three elements:

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

M.P.E.P., 8th ed., § 2142.

As an initial matter, the question of whether an obviousness-type double patenting rejection is correct cannot be answered without properly construing each set of claims: "Double patenting is altogether a matter of what is claimed." *General Foods Corp. v. Studiengesellschaft Kohle GmbH*, 972 F.2d 1272, 1277, 23 U.S.P.Q.2d 1839, 1343 (Fed. Cir. 1992). It is a fundamental rule of claim construction that every limitation is material and that what is claimed is what is defined by the claim as a whole. *Id.* at 1280, 23 U.S.P.Q.2d at 1845.

The Office Action states that claims 1-10 of Meyers are "drawn to a method for identifying a compound which modulates the activity of said kinase-like polypeptide . . . ." Office Action at page 5, first full paragraph. Claims 1-10 of Meyers do not simply recite "a kinase-like polypeptide"; each of claims 1-10 of Meyers recites a specific set of polypeptides which either (a) comprise Meyers' SEQ ID NO:2, (b) comprise at least 75 contiguous amino acids of Meyers' SEQ ID NO:2, or (c) which are encoded by a nucleic acid molecule which hybridizes to Meyers' SEQ ID NO:1, nucleotides 191-1156 of Meyers' SEQ ID NO:1, or a complement thereof under particular recited stringent hybridization conditions. The pending claims are not obvious over claims 1-10 of Meyers at least because, as demonstrated below, none

of the recited polypeptides or nucleic acid molecules is obvious over those in claims 1-10 of Meyers.

Appendix 1 shows the results of a BLAST alignment between Meyers' SEQ ID NO:2 with SEQ ID NO:2 of the present application. The BLAST algorithm detected no significant similarity between the two sequences. There is no legal or scientific argument which supports a contention that the 14189 polypeptide is obvious over a polypeptide with no significant similarity.

Appendix 2 shows the results of a BLAST alignment between SEQ ID NO:1 of the present application and SEQ ID NO:1 of Meyers and with the reverse complement of Meyers' SEQ ID NO:1. In each case, the BLAST algorithm detected no significant similarity between the sequences recited in the pending claims and those of Meyers. As with the polypeptides discussed above, there is no legal or scientific argument which supports a contention that Applicants' SEQ ID NO:1 is obvious over a nucleotide sequence which bears no significant similarity to it.

Finally, Meyers defines the term "hybridizes under stringent conditions" as describing "conditions for hybridization and washing under which nucleotide sequences having at least about 60%, 65%, 70%, preferably 75% identity to each other typically remain hybridized to each other." Col. 12, lines 15-20. None of Applicants' recited nucleic acid molecules could meet this standard and therefore could not be obvious over unspecified molecules which do.

Meyers' claims 1-10 do not provide the three elements required to make a *prima facie* case of obviousness. Claims 1-10 do not teach or suggest all the elements of Applicants' claimed methods, nor is there any suggestion or motivation, either in claims 1-10 themselves or

in the knowledge generally available to one of ordinary skill in the art, to modify Meyers' recited sequences.

Please withdraw the rejection.

Respectfully submitted,

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/Lisa M. Hemmendinger/

Dated: January 14, 2008 By: _____

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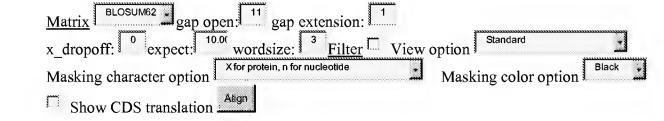
APPENDIX 1. BLAST ALIGNMENT OF MEYERS' SEQ ID NO:2 WITH APPLICANTS' SEQ ID NO:2.

Note: Applicants' SEQ ID NO:2 contains "Xaa," so the BLAST alignment was carried out with two separate pieces of SEQ ID NO:2 (amino acids 1-223 and amino acids 225-544; "Xaa" is amino acid 224).

BLAST 2 SEQUENCES RESULTS VERSION BLASTP 2.2.17 [Aug-26-2007]



Sequence 1: SEQ ID NO:2 of Meyers
Length = 322

Sequence 2: amino acids 1-223 of Applicants' SEQ ID NO:2
Length = 223

No significant similarity was found

```
CPU time:      0.05 user secs.      0.02 sys. secs          0.07 total secs.
```

Sequence 1: SEQ ID NO:2 of Meyers
Length = 322

Sequence 2: amino acids 225-544 of Applicants' SEQ ID NO:2
Length = 320

No significant similarity was found

```
CPU time:      0.06 user secs.      0.02 sys. secs          0.08 total secs.
```

APPENDIX 2. BLAST ALIGNMENT OF MEYERS' SEQ ID NO:1 WITH APPLICANTS' SEQ ID NO:1.

BLAST 2 SEQUENCES RESULTS VERSION BLASTN 2.2.17 [Aug-26-2007]

Match: 1 Mismatch: -2 gap open: 5 gap extension: 2
x_dropoff: 0 expect: 10.0 wordsize: 11 Filter ☐ View option Standard
Masking character option X for protein, n for nucleotide Masking color option Black
☐ Show CDS translation Align

Sequence 1: SEQ ID NO:1 of Meyers
Length = 1586

Sequence 2: SEQ ID NO:1 of Applicants
Length = 1918

No significant similarity was found
```
CPU time:      0.07 user secs.      0.04 sys. secs          0.11 total secs.
```

Sequence 1: SEQ ID NO:1 of Meyers
Length = 1586

Sequence 2: reverse complement of SEQ ID NO:1 of Applicants
Length = 1917

No significant similarity was found
```
CPU time:      0.07 user secs.      0.04 sys. secs          0.11 total secs.
```